

## I. AMENDMENTS TO THE CLAIMS

Claim 1. (Currently Amended) A method of solubilizing diterpenes at least one natural or synthetic forskolin, isoforskolin, or 7-deacetylforskolin 7-deacetylforskolin, of natural or synthetic origin, individually or as mixtures, in water, the method comprising the following operations:

- 1) suspending Forskolin forskolin, isoforskolin or 7-deacetyl**forskolin** in water containing a complexing/solubilizing cyclodextrin agent, wherein the cyclodextrin agent is the sole complexing/solubilizing agent;
- 2) agitating at room temperature; and
- 3) filtering to obtain a clear aqueous solution containing 0.09% to 6% of forskolin, isoforskolin, or 7-deacetyl**forskolin**.

Claim 2. (Currently Amended) The method as claimed in claim 1, wherein the at least one natural diterpenes forskolin, isoforskolin, or 7-deacetylforskolin of Claim 1 is obtained from a plant source Coleus forskohlii.

Claim 3. (Currently Amended) A method as claimed in claim 1 The method as claimed in claim 1, wherein the complexing/solubilizing cyclodextrin agent is chosen selected from the group consisting of  $\alpha$ -,  $\beta$ -,  $\gamma$ -cyclodextrins or their derivatized products, randomly methylated  $\beta$ -cyclodextrin (RAMEBCD), 2-hydroxy-propyl- $\beta$ -cyclodextrin (HPBCD), and hydroxypropyl  $\gamma$ -cyclodextrin (HPGCD) as the complexing/solubilizing agent.

Claim 4. (Currently Amended) A method of preparing a clear aqueous solution containing 0.09% to 6% diterpenes forskolin, isoforskolin, 7-deacetylforskolin by mixing the compound with 5% 70% cyclodextrin or cyclodextrin derivatives The method as claimed in claim 3, wherein prior to step 1), the cyclodextrin agent and forskolin, isoforskolin, or 7-deacetylforskolin are dissolved in a solvent under agitation, wherein the solvent is chosen from selected from the group consisting of ethanol, acetone, ethyl acetate, and methylene chloride under agitation to solubilize, followed by removal of the solvent and suspending and dissolving the residue in water.

Claim 5. (Currently Amended) A method of solubilizing at least one natural or synthetic forskolin, isoforskolin, or 7-deacetyl forskolin in water, the method comprising:

- 1) dissolving forskolin, isoforskolin or 7-deacetyl forskolin in an organic solvent selected from ethanol, acetone, ethyl acetate, methylene chloride;
- 2) recrystallizing forskolin, isoforskolin or 7-deacetyl forskolin from the organic solvent;
- 3) complexing the forskolin, isoforskolin or 7-deacetyl forskolin in water containing a complexing/solubilizing cyclodextrin agent selected from the group consisting of  $\alpha$ -,  $\beta$ -,  $\gamma$ -cyclodextrins or their derivatized products, randomly methylated  $\beta$ -cyclodextrin (RAMEBCD), 2-hydroxy-propyl- $\beta$ -cyclodextrin (HPBCD), and hydroxypropyl  $\gamma$ -cyclodextrin (HPGCD), wherein the cyclodextrin agent is the sole complexing/solubilizing agent;
- 4) agitating at room temperature for 4 to 160 hours; and
- 5) filtering to obtain a clear aqueous solution containing 0.09% to 6% of forskolin, isoforskolin, or 7-deacetyl forskolin

~~method, as claimed in claim 1, wherein the active compound is recrystallized from an organic solvent selected from ethanol, acetone, ethyl acetate, methylene chloride followed by complexation with cyclodextrin or cyclodextrin derivatives claimed in claim 3 by forming a suspension of the materials in water followed by agitation at room temperature for 4 to 160 hours and filtration to form a clear aqueous solution.~~

Claim 6. (Currently Amended) A method, as claimed in claim 1, of preparing a clear aqueous formulation containing 0.09% - 6% diterpenes forskolin, Isoforskolin, 7-deacetyl forskolin The method of claim 1, wherein the clear aqueous solution is suitable for ophthalmic, topical and systemic uses.

Claim 7. (Canceled)

Claim 8. (Currently Amended) A method for the treatment of glaucoma or ocular hypertension in a human or animal, the method comprising administering a clear aqueous solution comprising between 0.09% to 6% of at least one natural or synthetic forskolin, isoforskolin, or 7-deacetyl forskolin complexed with a cyclodextrin agent,

wherein the cyclodextrin agent is the sole complexing/solubilizing agent of use of the formulation of claim 6 alone or in combination with antioxidants and/or anti-glaucoma agents, in lowering intraocular pressure in animals or human subjects presenting with ocular hypertension or glaucoma.

Claim 9. (Currently Amended) A method for the treatment of dry eye syndrome in a human or animal, the method comprising administering a clear aqueous solution comprising between 0.09% to 6% of at least one natural or synthetic forskolin, isoforskolin, or 7-deacetyl forskolin complexed with a cyclodextrin agent, wherein the cyclodextrin agent is the sole complexing/solubilizing agent of use of the formulation of claim 6 alone or in combination with polyvinyl pyrrolidone, hyaluronic acid and derivatives, in animals or human subjects presented with dry eye syndrome.

Claims 10 to 14. (Canceled)

Claim 15. (New) A method for the treatment of glaucoma or ocular hypertension in a human or animal, the method comprising administering a clear aqueous solution comprising between 0.09% to 6% of at least one natural or synthetic forskolin, isoforskolin, or 7-deacetyl forskolin complexed with a cyclodextrin agent in combination with one or more antioxidants, wherein the cyclodextrin agent is the sole complexing/solubilizing agent.

Claim 16. (New) A method for the treatment of glaucoma or ocular hypertension in a human or animal, the method comprising administering a clear aqueous solution comprising between 0.09% to 6% of at least one natural or synthetic forskolin, isoforskolin, or 7-deacetyl forskolin complexed with a cyclodextrin agent in combination with one or more anti-glaucoma agents, wherein the cyclodextrin agent is the sole complexing/solubilizing agent.

Claim 17. (New) A method for the treatment of dry eye syndrome in a human or animal, the method comprising administering a clear aqueous solution comprising between 0.09% to 6% of at least one natural or synthetic forskolin, isoforskolin, or 7-

deacetyl forskolin complexed with a cyclodextrin agent and hyaluronic acid derivatives, wherein the cyclodextrin agent is the sole complexing/solubilizing agent.

Claim 18. (New) A method for the treatment of dry eye syndrome in a human or animal, the method comprising administering a clear aqueous solution comprising between 0.09% to 6% of at least one natural or synthetic forskolin, isoforskolin, or 7-deacetyl forskolin complexed with a cyclodextrin agent and polyvinyl pyrrolidone, wherein the cyclodextrin agent is the sole complexing/solubilizing agent.

Claim 19. (New) A method of solubilizing at least one natural or synthetic forskolin, isoforskolin, or 7-deacetyl forskolin in water, the method comprising:

- 1) suspending forskolin, isoforskolin or 7-deacetyl forskolin in water containing RAMEBCD;
- 2) agitating at room temperature; and
- 3) filtering to obtain a clear aqueous solution containing 0.09% to 6% of forskolin, isoforskolin, or 7-deacetyl forskolin.

Claim 20. (New) A clear aqueous solution comprising between 0.09% to 6% of at least one natural or synthetic forskolin, isoforskolin, or 7-deacetyl forskolin complexed with RAMEBCD.

Claim 21. (New) A method for the treatment of glaucoma in a human or animal comprising administering the clear aqueous solution of claim 20.

Claim 22. (New) A method for the treatment of ocular hypertension in a human or animal comprising administering the clear aqueous solution of claim 20.

Claim 23. (New) A method for the treatment of dry eye syndrome in a human or animal comprising administering the clear aqueous solution of claim 20.